

REMARKS

Claims 16, 26-33, 37, and 40-57 are pending in this application. Claims 41-50 are withdrawn pending rejoinder if product claims are allowed. Claims 52 and 54 are amended. Claim 38 is cancelled.

New Matter

In an effort to further prosecution of this application, claims 52 and 54 have been amended to remove the term PEGylation. The Applicants do not concede this amendment is necessary and reserve the right to prosecute claims with this term in one or more continuation applications. We note that claim 54 is not currently subject to any other rejection and assume claim 52 also was not intended to be rejected. The amendments to claims 52 and 54 are believed to satisfy the Examiner's concerns and the Applicants request that this rejection be withdrawn.

35 U.S.C. § 112, first paragraph (Enablement)

Claims 16, 26-31, 33, 37, 38, 40, 51-52, and 55-57 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to enable claims to an isolated polypeptide comprising at least 17, 20, 25, 30, 35, 50, or 75 amino acids of SEQ ID NO:2, or variants of SEQ ID NO:2. Claim 38 is cancelled.

The Applicants respectfully point out that the test for enablement is whether experimentation alleged to be necessary is undue, *not whether any experimentation is necessary*. *In re Angstadt*, 537 F.2d 498, 504 (CCPA 1976). When the art typically engages in a type of experimentation, that experimentation is not considered undue. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Claim 16, for example, recites a finite number of sequences (as opposed to an *infinite* number of sequences as asserted in the Office Action). Specifically, SEQ ID NO:2 contains 242 amino acids, thus, there are 225 (i.e., 242 minus 17) possible 17 amino acid sequences contained in SEQ ID NO:2. The possible number of sequences decreases as the specified number of amino

acids in a fragment increases, i.e., a 20 amino acid fragment has 222 possible sequences (claim 26), a 25 amino acid fragment has 217 possible sequences (claim 27), etc. The Applicants point out, for example, that claim 31 pertains to only 167 fragments. It is easily within the skill of a skilled artisan to generate (*see, e.g.*, p. 31, lines 10-16) and identify (*see, e.g.*, p. 33-36 and 54 (line 12)-55 (line 9)) a set of at most 225 seventeen amino acid fragments and test for WSX-1/TCCR binding. The samples could be run in a single assay by one of skill in the art using routine methods and the teachings herein.

The Applicants also note that the Examiner has indicated that a fragment of 17 amino acids is unlikely to possess the desired functional property, i.e., binding to WSX-1/TCCR. The Applicants request that the Examiner provide some evidence for this assertion.

The Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

35 U.S.C. § 112, first paragraph (Written Description)

Claims 16, 26-31, 33, 37, 38, 40, 51-52, and 55-57 are rejected under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter not adequately described in the specification.

The Court of Appeals for the Federal Circuit requires that a specification convey with reasonable clarity to those of skill in the art that, as of the filing date sought, the inventor was in possession of the subject matter claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Further, MPEP § 2163.02 states that “[t]he subject matter of the claim need not be described literally (*i.e.*, using the same terms in *haec verba*) in order for the disclosure to satisfy the description requirement.” In this case, the Applicants have conveyed with more than reasonable clarity the subject matter of their claims to those of skill in the art.

The claims are directed to various length polypeptide fragments of SEQ ID NO:2, which is a 242 amino acid polypeptide. The complete amino acid sequence of SEQ ID NO:2 is listed in the sequence listing as well as being shown in Fig. 1. The specification discloses several specific sections, i.e., polypeptides, of SEQ ID NO:2 at p. 8 as follows:

A predicted signal cleavage site may exist between about residues 25-30 of SEQ ID NO: 2; helix A is predicted to run from about residues 33-38 to about residues 54-59 of SEQ ID NO: 2; helix B is predicted to run from about residues 85-90 to about residues 111-116 of SEQ ID NO: 2; helix C is predicted to run from about residues 121-126 to about residues 154-159 of SEQ ID NO: 2; and helix D is predicted to run from about residues 201-206 to about residues 228-233 of SEQ ID NO: 2.

With respect to the disclosed sequences, the specification further indicates at p. 10 that “[t]hese amino acid sequences . . . are important in providing sequence information for the cytokine allowing for distinguishing the protein antigen from other proteins and exemplifying numerous variants.” Moreover, the peptide sequences allow preparation of peptides to generate antibodies to recognize such segments” Additionally, a polypeptide is defined at p. 11 to include

a significant fragment or segment, and encompasses a stretch of amino acid residues of at least about 8 amino acids, generally at least about 12 amino acids, typically at least about 16 amino acids, preferably at least about 20 amino acids, and, in particularly preferred embodiments, at least about 30 or more amino acids, e.g., 35, 40, 45, 50, 60, 75, 100, etc. Such fragments may have ends which begin and/or end at virtually all positions, e.g., beginning at residues 1, 2, 3, etc., and ending at, e.g., 150, 149, 148, etc., in all practical combinations. Particularly interesting peptides have ends corresponding to structural domain boundaries, e.g., helices A, B, C, and/or D.

Further, in addition to other portions of the specification, synthetic methods for producing polypeptides and polypeptide fragments of SEQ ID NO:2 are disclosed at p. 31. Finally, Example XII. D. shows that IL-27 binds to WSX-1/TCCR. Thus, the polypeptides and polypeptide fragments that bind to WSX-1/TCCR as claimed are well-defined by SEQ ID NO:2. Given the fact that SEQ ID NO:2 is provided, as well as methods for polypeptide synthesis and screening, one of skill in the art would clearly perceive a defined set of peptide fragments.

As noted by the Federal Circuit, “an adequate written description of a [biological molecule] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the [biological molecule]

itself.”” *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997) (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed.Cir.1993)). In the instant case, the Applicants have provided SEQ ID NO:2, which contains each of the sequences recited by the claims. Further, methods for synthesizing peptides are disclosed and well known in the art, and methods of making and using the claimed polypeptides are also provided. Given all the information provide in the specification, one of skill in the art would consider the subject matter of the claims clearly articulated. For these reasons, the Applicants respectfully request reconsideration and withdrawal of the written description rejection.

Conclusions

For the reasons set forth above, the Applicants submit that the claims of this application are allowable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested.

It is believed that all issues raised by the Examiner have been addressed. However, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at 404-892-5005.

No fees are believed to be due with the filing of this Amendment. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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